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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,355

01/14/2004

Matthias Blau

BLAU

3324

20151 7590 06/11/2007  
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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

06/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/757,355

Applicant(s)

BLAU ET AL.

Examiner

Sara Lustusky

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-33 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-33 and 35-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

The Examiner acknowledges Applicant's amendment dated 12 February 2007. Claims 22, 37, 38 and 43 are amended. Claim 34 is cancelled. Claims 22-33 and 35-43 are pending.

### ***Drawings***

The drawings were received on 12 February 2007. These drawings are acceptable and over the drawing objections set forth in the Office Action dated 10 August 2006.

### ***Specification***

In view of Applicant's amendments to the abstract, the rejections of the abstract set forth in the Office Action dated 10 August 2006 are withdrawn.

### ***Claim Rejections - 35 USC § 112***

In view of Applicant's amendments to the claims, the rejections under 35 USC 112, second paragraph set forth in the Office Action dated 10 August 2006 are withdrawn.

### ***Claim Rejections - 35 USC § 101***

In view of Applicant's amendments to the claims, the rejections under 35 USC 101 set forth in the Office Action dated 10 August 2006 are withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 22-29, 31-33 and 37-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over by Ball et al. (US 2001/0003788 A1) in view of Nunley et al. (US 3882285 A).

Ball et al. teaches an implantable electromechanical converter (100) comprising: a hermetically sealed hollow body (10, 320, 340, 360) made of a biocompatible material, said hollow body (10, 320, 340, 360) having a thin shell with an exterior side coupled to the ear ossicle and an interior side (as described in lines 3-12 of paragraph [0082]); at least one piezoelectric converter element housed in the hollow body and coupled the interior side of the thin shell (as described in lines 4-10 of paragraph [0122]), and a stable edge supporting the thin shell, said stable edge being coupled to a counter-support in the middle ear space (as described in lines 4-10 of paragraph [0081]); wherein the stable edge is taught as being generally a cylindrical shape (as described in lines 6-8 of paragraph [0082]), which the examiner considers to include elliptical shapes; wherein the hollow body includes a means for limiting an excursion of the thin shell (as described in paragraphs [0124] and [0125]); wherein the biocompatible material of the hollow body comprises titanium or a titanium alloy (as described in lines 3-4 of paragraph [0125]); wherein the thin shell is formed as a plate (as seen in

Art Unit: 3735

embodiment in Figure 4), the hollow body (10) having a diameter of 1mm and a thickness of 1mm (as described in lines 16-18 of paragraph [0091]), and therefore inherently the thin shell may have a thickness of a range including thicknesses between 20 and 50 micrometers; wherein the thin shell and the stable edge are formed as a single piece and are shaped by a mechanical separation or forming process or an etching process (as described in lines 3-4 of paragraph [0125]); wherein the at least one piezoelectric converter element (308, 310, 326, 328) (as seen in Figures 13 and 15a, 15b) comprises an element selected from the group consisting of a piezoelectric ceramic material, a piezoelectric film, and a piezoelectric single crystal (as described in lines 8-10 of paragraph [0122]); wherein the at least one piezoelectric converter element (308, 310, 326, 328) is mechanically supported on the interior side of the thin shell of the housing (302) (as seen in Figures 13 and 15a, 15b); wherein the at least one piezoelectric converter element is implemented as unimorphic or multimorphic bending plate or bending beam (308, 310, 326, 328) (as seen in Figures 13 and 15a, 15b) (as described in lines 8-10 of paragraph [0122]); wherein the at least one piezoelectric converter element is secured within the thin shell (as described in lines 8-9 of paragraph [0128]); wherein the thin shell is coupled to the articular cartilage of the severed incus-stapes joint that is coupled with the long incus appendage (as seen in the embodiment of Figures 7 and 9); further comprising a post (40, 40c) made of a biocompatible material (as described in the embodiment in lines 1-2, 7-9 and 12-14 of paragraph [0104]), said post (40, 40c) forming a counter-support which is supported on a first end in a recess of the oval window (EE) (for purposes of examination the examiner

Art Unit: 3735

considered "the oval window" to mean reference character "6" as seen in Figure 2 of the Drawings) and is configured on a second other end to receive the stable edge (as seen in the embodiments in Figures 8 and 9); wherein the post (40, 40c) includes a means for anchoring the post in a bone canal of the stapes tendon (as seen in Figures 8 and 9); wherein the post (40, 40c) includes positioning means for positioning the thin shell relative to the coupled ear ossicle (as described in lines 8-11 of paragraph [0104]) (as seen in Figures 8 and 9); wherein the positioning means are implemented as insertable support plates or wedges made of a biocompatible material (as described in the embodiment in lines 1-2, 7-9 and 12-14 of paragraph [0104]) which are inserted between the post (40, 40c) and the stable edge (as seen on each end of 40 and 40c in Figures 8 and 9), wherein it would have been obvious to one of ordinary skill in the art at the time of the invention to weld a connection between the thin shell and the stable edge as this is an obvious variant in the art to the process of machining and would produce an equivalent product. Ball et al. however does not teach that an electronic circuit for conditioning the electrical voltage is located inside the hollow body.

Nunley et al. teaches an implantable hearing device comprising an implantable hollow body adapted to be coupled to the ear ossicle and coupled to a counter support in the middle ear space, wherein an electronic circuit for conditioning electrical voltage is located inside the hollow body (as described in lines 5-24 of column 3).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include an electronic circuit for conditioning electrical voltage similar to that of Nunley et al. within a hollow body of an implantable electromechanical converter

Art Unit: 3735

similar to that of Ball et al. in order to eliminate the needle for multiple components and for the implantation of cables or wires to couple each component together as these may cause irritation. Furthermore, while Ball et al. teaches that the at least one piezoelectric converter element is secured; it is not expressly taught that the piezoelectric converter element is secured by adhesive. However, securing means are taught which include adhesive (as described in lines 4-14 of paragraph [0081]). It would have been obvious to one of ordinary skill in the art at the time of the invention to secure the piezoelectric converter element using adhesive in view of the teachings of Ball et al. because the piezoelectric converter element works by deformation and thus requires at least a portion to be braced to provide a resistive force against which to deform. In view of the teachings of Ball et al., adhesive can be used to secure the piezoelectric converter element to provide a resistive force.

**Claim 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ball et al. (US 2001/0003788 A1) and Nunley et al. (US 3882285 A) as applied to claims 22 and 29 above, in view of Wang et al. (US 6627104 B1).

The combination of Ball et al. and Nunley et al. teaches the converter of claims 22 and 29, as described above, comprising a hollow body having a thin shell, coupled to an ossicle and at least one piezoelectric converter element housed in the hollow body. Ball et al. teaches that the piezoelectric converter element may be made of any piezoelectric material, however materials PZN-PT and PMN-PT were not expressly taught.

Wang et al. teaches the use of piezoelectric materials for use in electronic and microelectronic devices, the materials taught include lead zinc niobate-lead titanate (PZN--PT) or lead magnesium niobate-lead titanate (PMN--PT) (as described in lines 41-55 of column 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to make a piezoelectric converter element similar to that taught by the combination of Ball et al. and Nunley et al. from PMN-PT or PZN-PT as taught by Wang et al. The materials taught by the combination of Ball et al. and Nunley et al. can be substituted with the materials taught by Wang et al. as a design choice because they have similar piezoelectric properties (as described in lines 41-55 of column 1 of Wang et al.).

**Claims 35 and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ball et al. (US 2001/0003788 A1) and Nunley et al. (US 3882285 A) as applied to claim 22 above, in view of Berrang et al. (US 2002/0019669 A1).

The combination of Ball et al. and Nunley et al. teaches the converter of claim 22, as described above, comprising a hollow body having a thin shell, and at least one piezoelectric converter element housed in the hollow body, and electric wires (24) extending through a feedthrough (26) to connect to provide an external connection to the electrical voltage (as described in the embodiment of lines 13-15 of paragraph [0097]), but does not teach that the feedthrough is electrically insulated.



Berrang et al. teaches an implantable electronic device comprising sealed, electrically insulating feedthroughs, wherein the insulating materials include a material selected from the group consisting of glass, ceramics and minerals (as described in lines 1-5 of paragraph [0023] and lines 1-2 and 4-6 of paragraph [0079]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to insulate the sealed feedthroughs of a device similar to that taught by the combination of Ball et al. and Nunley et al. with insulating materials similar to those taught by Berrang et al. because it is commonly known in the art that implantable electrical components should be insulated to protect the device and to protect the patient and that glass, ceramics and minerals are commonly used insulating materials known in the art.

**Claims 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ball et al. (US 2001/0003788 A1) and Nunley et al. (US 3882285 A) as applied to claims 22, 38-40 above, in view of Bushek et al. (US 5836863).

The combination of Ball et al. and Nunley et al. teaches the converter of claims 22 and 38-40, as described above, comprising a hollow body having a thin shell, and at least one piezoelectric converter element housed in the hollow body, which is coupled to an ossicle and has a counter support, which is taught as a post in an alternative embodiment. While Ball et al. teaches various mounting mechanisms, including screws and a support element having two ends, it is not expressly taught that these mechanisms are combined, or that the post comprises two segments.

Bushek et al. teaches a piezoelectric converter element (115, 120) with a counter-support (110) having two ends, with one end being connected with the stable edge and the other end being connected with a bone by a screw (130) connection (as seen in Figures 1A, 1B, 2 and 3). Bushek et al. also teaches that the counter support may be in the form of a post comprising two segments that are adapted to be lockably engaged (as seen in Figures 4A, B, C and 5A, B, C).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine supports similar to those taught by Ball et al. to form a counter-support similar to that as taught by Bushek et al. to support a piezoelectric converter element similar to that of Ball et al. because it is a functional equivalent that provides variety for dealing with different patient anatomies and different ossicle or middle ear defects (as described in lines 9-10 and 35-45 of column 7 of Bushek et al.).

### ***Response to Arguments***

Applicant's arguments dated 12 February 2007, with respect to the rejection(s) of claim(s) 22-43 under 35 USC 102 and 103 have been fully considered. The indicated allowability of canceled claim 34 is withdrawn based on further consideration of the Nunley et al. patent. Therefore, the rejections set forth in the Office action of 10 August 2006 have been withdrawn. However, upon further consideration, new grounds of rejection are made in view of the combination of Ball et al. and Nunley et al.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jaeger (US 6422991 B1) teaches an implantable hollow body

Art Unit: 3735


coupled to the ossicles of the ear, wherein an electronic circuit for conditioning the electrical voltage is located within the hollow body but does not teach that said hollow body is located and coupled within the middle ear space of a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.L.

  
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Supervisory Patent Examiner  
Art Unit 3735